

JS 44 (Rev. 06/17) - TXND (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Rogelio Rios and Lidia rios-Vilchis

(b) County of Residence of First Listed Plaintiff Bexar
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Nicole E. Henning, 435 W. Nakoma, Suite 101, San Antonio, TX 78216
210-563-7828

DEFENDANTS

Daval, Inc., and C. R. Bard

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 490 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$
2,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

08/22/2019

SIGNATURE OF ATTORNEY OF RECORD

/s/ Nicole E. Henning

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS**

**ROGELIO RIOS and
LIDIA RIOS-VILCHIS**

Plaintiffs,

V.

**DAVOL INC., and
C.R. BARD,**

Defendants.

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**Civil Action No.:** \_\_\_\_\_

## JURY TRIAL DEMANDED

Plaintiff, by and through his undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of the Defendants' hernia mesh product. As a result, Plaintiff Rogelio Rios permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which Plaintiff may be legally entitled.

## **STATEMENT OF PARTIES**

2. Plaintiff is, and was, at all relevant times, a resident of Texas and the United States.

3. Davol, Inc. (“Daval”) is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research,

development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including inguinal dart shaped hernia meshes composed of polypropylene known as the Bard Mesh PerFix Plug (hereinafter “PerFix Plug”).

4. C.R. Bard, Inc. (“Bard”) is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. Bard is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the PerFix Plug. It also manufactures and supplies Davol with material that forms part of the Bard Mesh PerFix Plug.

5. Bard was, at all times relevant hereto, responsible for the actions of Davol and exercised control over Davol’s functions specific to the oversight and compliance with applicable safety standards relating to and including PerFix Plug sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants’ design, manufacture, marketing, labeling, distribution, sale and placement of its defective PerFix Plug at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees

and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

**VENUE AND JURISDICTION**

8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds \$75,000.00.

9. Venue is proper in this Court pursuant to 28 U.S.C. §1332(a)-(c) by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendant's products are sold to and consumed by individuals in the State of TEXAS, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

10. Defendants have and continue to conduct substantial business in the State of TEXAS and in this District, distribute PerFix Plug in this District, receive substantial compensation and profits from sales of PerFix Plug in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

11. Davol is registered to transact business in TEXAS.

**FACTS COMMON TO ALL COUNTS**

12. On or about February 18, 2010 Plaintiff ROGELIO RIOS underwent left inguinal hernia repair by Dr. DILMA C. RUIZ-FRIEL at Baptist Health System in San Antonio, Texas. A small PerFix Plug, REF No. 0112760, Lot No. HUSI0487 was implanted in Plaintiff during this repair.

13. Defendants, manufactured, sold, and/or distributed the PerFix Plug to Plaintiff,

through Plaintiff's doctors, to be used for treatment of hernia repair.

14. Plaintiff began to experience pain due to Defendant's plug mesh in or around April 2018.

15. Plaintiff continues to suffer severe groin pain and sexual dysfunction to date.

16. Defendant's PerFix Plug is a three-dimensional hernia mesh containing layers of polypropylene with a separate pre-shaped on-lay polypropylene patch, and it is marketed by Defendants as a mesh to be used in repairing hernias.

17. Defendants' PerFix Plug product contains several layers of polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving these products. This immune response promotes degradation and contracture of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

18. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

19. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

20. PerFix Plug contains the following components:

A) Several layers of polypropylene constructed as a fluted outer layer  
with multiple inner layers, and

B) One layer of pre-shaped polypropylene mesh with the option to be

implanted as an on-lay over the plug once implanted.

21. Defendants' PerFix Plug can contract up to 70% post implantation.

22. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of PerFix Plug, including providing the warnings and instructions concerning the product.

23. Among the intended purposes for which Defendants designed, manufactured and sold PerFix Plug was use by surgeons for hernia repair surgeries, the purpose for which the PerFix Plug was implanted in Plaintiff.

24. Defendants represented to Plaintiff and Plaintiff's physicians that PerFix Plug was a safe and effective product for hernia repair.

#### **ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

25. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

26. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

27. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicated that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

28. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the PerFix Plug was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of

limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suits were filed well within the applicable statutory limitations period.

29. The running of the statute of limitations in this cause of action is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the PerFix Plug. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

**COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT**

30. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

31. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the product was sold.

32. The implantation of PerFix Plug in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

33. At the time the PerFix Plug that was implanted in Plaintiff's body, the product was defectively manufactured.

34. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the PerFix Plug implanted in Plaintiff. The PerFix Plug implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

35. Upon information and belief, Defendants utilized substandard and adulterated polypropylene in the PerFix Plug, which deviated from Defendants' material and supply specifications.

36. As a direct and proximate result of the defective manufacture of the PerFix Plug, Plaintiff suffered injuries and damages as summarized herein.

**COUNT II: STRICT LIABILITY – DESIGN DEFECT**

37. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

38. Defendants' PerFix Plug was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the PerFix Plug, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; sexual dysfunction; damage to reproductive organs; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

39. The PerFix Plug includes a tapered design, which promotes mesh migration in the direction of the taper.

40. The three-dimensional design of the PerFix Plug promotes mesh contracture or the mesh "wadding," "balling," or "knuckling" up.

41. Mesh porosity impacts tissue ingrowth and the inflammatory response. Mesh pore size should be at least 3mm. Pore sizes small than 3mm decreases tissue incorporation, increases



inflammation, and results in a fibrotic reaction. The PerFix Plug has a mesh pore size of 1mm.

42. The PerFix Plug has multiple layers of polypropylene, increasing the mesh surface area and foreign body load, which increases the inflammatory and foreign body response.

43. The polypropylene weave of the PerFix Plug produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

44. Observation of mesh under the scanning electron microscope reveals that very small interstices exists between the PerFix Plug mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some Bacteria are capable of degrading polypropylene.

45. These manufacturing and design defects associated with the PerFix Plug were directly and proximately related to the injuries suffered by Plaintiff.

46. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of PerFix Plug. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the PerFix Plug.

47. The PerFix Plug implanted in Plaintiff failed to reasonably perform as intended. The PerFix Plug caused serious injury and has to be surgically removed via invasive surgery, and necessitate additional invasive surgery to repair the hernia that the PerFix Plug was initially implanted to treat.

48. At the time the PerFix Plug that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the PerFix

Plug would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

49. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the PerFix Plug was sold.

50. The implantation of PerFix Plug in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the PerFix Plug.

51. The risks of the PerFix Plug significantly outweigh any benefits that Defendants contend could be associated with the PerFix Plug. The dart-like design, which is not used in any other hernia mesh product sold in the United States, promotes mesh migration and incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, erosion, rejection and further migration.

52. The polypropylene mesh utilized to manufacture the PerFix Plug was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the PerFix Plug. The particular polypropylene material used in the PerFix Plug was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted adjacent internal organs, structures, nerves, arteries, and vessels, as Defendants intended for PerFix Plug, polypropylene mesh is unreasonably susceptible to adhesion formation, nerve entrapment, spermatic cord obliteration, organ perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

53. The appropriate treatment for complications associated with PerFix Plug involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported

benefit that the mesh was intended to provide to the patient.

54. At the time the PerFix Plug was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, single-layer, porous mesh.

55. The PerFix Plug product cost significantly more than competitive products because of its unique dart shape, even though the dart shape provided no benefit to consumers, and increased the risks to patients implanted with these devices.

56. The PerFix Plug implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

57. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

**COUNT III: STRICT LIABILITY – FAILURE TO WARN**

58. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

59. At the time the PerFix Plug that was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the PerFix Plug were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

60. Defendants expected and intended the PerFix Plug product to reach users such as Plaintiff in the condition in which the product was sold.

61. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of PerFix Plug, and were unaware of the frequency, severity and duration of the risks associated with the PerFix Plug.

62. The Defendants' Instructions for Use provided with the PerFix Plug is silent on the fact that the PerFix Plug has a propensity to migrate post implantation in the direction of the taper. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique dart-like design of the PerFix Plug.

63. The Defendants' Instructions for Use for the PerFix Plug failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the PerFix Plug, including the risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

64. Defendants failed to adequately warn implanting surgeons of the significant risk of complications associated with mesh migration if the PerFix Plug is implanted in the groin to repair an inguinal hernia.

65. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the PerFix Plug, or how to properly treat such complications when they occurred.

66. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the PerFix Plug in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed

PerFix Plug was intended to treat.

67. Defendants represented to physicians, including Plaintiff's physician, that the tapered design would prevent or reduce recurrences and pain, and expressly intended for the PerFix Plug to be implanted near numerous large nerves and organs, and marketed and promoted the PerFix Plug for said purpose. Defendants failed to warn physicians that the PerFix Plug would contract over time, increases the rates of recurrence and the ability of the PerFix Plug to migrate.

68. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with PerFix Plug were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

69. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of PerFix Plug, and of the frequency, severity and duration of the risks associated with the PerFix Plug, Plaintiff would not have consented to allow the PerFix Plug to be implanted, and Plaintiff's physicians would not have implanted the PerFix Plug in Plaintiff.

70. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

#### **COUNT IV: NEGLIGENCE**

71. Plaintiffs incorporate herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

72. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for PerFix Plug, but failed to do so.

73. Defendants knew, or in the exercise of reasonable care should have known, that PerFix Plug was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom PerFix Plug was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the PerFix Plug.

74. Defendants knew or should have known that the Material Data Safety Sheet for the polypropylene used to manufacture its PerFix Plug prohibited permanently implanting the polypropylene into the human body.

75. Defendants utilized non-medical grade polypropylene.

76. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

77. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

78. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

79. Defendants knew or should have known that the tapered design of the PerFix Plug would promote mesh migration.

80. Defendants knew or should have known of the significant risk of complications if the PerFix Plug is implanted into the groin to repair a inguinal hernia. Nonetheless, Defendants marketed the PerFix Plug off-label as being safe and effective for inguinal and abdominal incisional hernia repair.

81. Defendants knew or should have known that small pore size and multiple layers of the PerFix Plug would increase mesh surface area and foreign body load, which would increase the inflammatory and foreign body response.

82. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for PerFix Plug, Plaintiff suffered injuries and damages as summarized herein.

#### **COUNT V: BREACH OF EXPRESS WARRANTY**

83. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

84. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the PerFix Plug.

85. In advertising, marketing, and otherwise promoting PerFix Plug to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their PerFix Plug was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting PerFix Plug, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant the PerFix Plug in their patients.

86. With respect to the Plaintiff, Defendants intended that PerFix Plug be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

87. Defendants expressly warranted to physicians, hospitals, other healthcare

providers and the general public including Plaintiff that the PerFix Plug was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' PerFix Plug.

88. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that the PerFix Plug was safe and fit for use for the repair of both groin and abdominal hernia.

89. The PerFix Plug was represented by the Defendants to prevent or minimize hernia recurrence and pain, and to facilitate incorporation of the mesh into the body, but it did not. Instead, the PerFix Plug caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

90. Defendant breached these express warranties because the PerFix Plug implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

91. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiffs physicians and healthcare providers, with respect to the PerFix Plug, including, but not limited to, the following particulars:

- A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' PerFix Plug was safe, meanwhile Defendants fraudulently



withheld and concealed information about the substantial risks of serious injury associated with using PerFix Plug.

- B. Defendants represented to Plaintiff and their physicians and healthcare providers that the Defendants' PerFix Plug was as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that PerFix Plug was not safer than alternative therapies and products available on the market; and
- C. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' PerFix Plug was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of PerFix Plug.

92. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy.

93. At the time of making such express warranties, Defendants knew or should have known that Defendants' PerFix Plug does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

#### **COUNT VI: BREACH OF IMPLIED WARRANTY**

94. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

95. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' PerFix Plug.

96. At all relevant times, Defendants intended that the Defendants' PerFix Plug be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each PerFix Plug and its component parts to be of merchantable quality, safe and fit for such use, and was not adequately tested.

97. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' PerFix Plug in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendants' PerFix Plug.

98. Plaintiff and/or Plaintiff's physicians were at all relevant times in privity with Defendants.

99. The Defendants' PerFix Plug was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

100. Defendants breached various implied warranties with respect to the PerFix Plug including the following particulars:

- A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' PerFix Plug was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the PerFix Plug;
- B. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that

the Defendants' PerFix Plug was safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the PerFix Plug was not safer than alternatives available on the market; and

- C. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' PerFix Plug was more efficacious than other alternative procedures and/or devices, and fraudulently concealed information, regarding the true efficacy of the PerFix Plug.

101. In reliance upon Defendants' implied warranty, Plaintiff individually and/or by and through Plaintiff's physician, used the PerFix Plug as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

102. Defendants breached their implied warranty to Plaintiff in that the Defendants' PerFix Plug was not merchantable quality, safe and fit for their intended use, or adequately tested.

103. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused and suffered severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

#### **COUNT VII: VIOLATION OF CONSUMER PROTECTION LAWS**

104. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

105. Plaintiff purchased and used the Defendants' PerFix Plug primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

106. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff

would not have purchased and/or paid for the Defendants' PerFix Plug, and would not have incurred related medical cost and injury.

107. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the PerFix Plug that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

108. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- A) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;
- B) Advertising goods or services with the intent not to sell them as advertised; and,
- C) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

109. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' PerFix Plug. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' PerFix Plug.

110. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' PerFix Plug.

111. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchases and/or paid for the PerFix Plug, and would not have incurred related medical cost.

112. Defendants' deceptive, unconscionable, or fraudulent representations and material

omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

113. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

114. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312 (1982)
- Mo Rev. Stat. §§ 407.010, et seq.
- N.J. Stat. Ann §§ 56:8-1, et seq.
- R.I. Gen. Laws §§ 6-13.1, et. seq.

115. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

116. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' PerFix Plug was fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

117. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair,

deceptive, fraudulent and unconscionable trade and business practices and false advertising.

118. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' PerFix Plug and failed to take any action to cure such defective and dangerous conditions.

119. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

120. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

121. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

122. As a direct and proximate result of Defendants' violations of the states; consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

#### **COUNT VIII: GROSS NEGLIGENCE**

123. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

124. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an

extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

125. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

126. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

127. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

#### **COUNT IX: UNJUST ENRICHMENT**

128. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

129. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' PerFix Plug.

130. Plaintiff paid for the Defendants' PerFix Plug for the purpose of treatment for hernia repair and/or a soft tissue injury or other similar condition.

131. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for

the purchase of the Defendants' PerFix Plug.

132. Plaintiff has not received the safe and effective medical device for which Plaintiff paid.

133. It would be inequitable for Defendants to keep this money, because Plaintiff did not in fact receive a safe and effective medical device.

**COUNT X: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

134. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

135. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' PerFix Plug to Plaintiff.

136. Defendants carelessly and negligently concealed the harmful effects of the Defendants' PerFix Plug from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

137. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the PerFix Plug to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

138. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the PerFix Plug sold and distributed by Defendants.

139. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.



140. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

141. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

**COUNT XI: FRAUDULENT CONCEALMENT**

142. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

143. At all times relevant hereto, it was known or knowable to Defendants that their Products caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its PerFix Plug had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the PerFix Plug was not safe and effective. Defendants continued to represent that its PerFix Plug was safe and effective.

144. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its PerFix Plug, Defendants failed to disclose this information to the Plaintiff, to Plaintiff's physicians, and to the public at large.

145. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the PerFix Plug, that is, that said

PerFix Plug was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiffs were implanted with Defendants' PerFix Plug.

146. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the PerFix Plug because:

- A) Defendants were in a superior position to know the true quality, safety, and efficacy of its PerFix Plug;
- B) Defendants knowingly made false claims about the safety and quality of its PerFix Plug in documents and marketing materials;
- C) Defendants fraudulently and affirmatively concealed the defective nature of the PerFix Plug from the Plaintiff.

147. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' PerFix Plug.

148. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians with the intent to defraud, as alleged herein.

149. Defendants intentionally concealed and/or failed to disclose the true defective nature of the PerFix Plug so that Plaintiff would request and purchase the Defendants' PerFix Plug, and their healthcare providers would dispense, prescribe, and recommend the Defendants' PerFix Plug, and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

150. At all times relevant hereto, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized Defendants' PerFix Plug in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' PerFix Plug. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

151. As a direct and proximate result of this conduct, Plaintiff was severely injured.

**COUNT XII: CONSTRUCTIVE FRAUD**

152. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

153. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the Defendants' PerFix Plug; knowledge that is not possessed by Plaintiff or Plaintiff's physicians. Defendants thereby hold a position of superiority over Plaintiff and Plaintiff's physicians.

154. Despite their unique and superior knowledge regarding the defective nature of the Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and the public concerning the severity and frequency of risks and dangerous inherent in the intended use of its PerFix Plug, as compared to other products and forms of treatment.

155. Defendants have concealed and suppressed material information that would reveal that the PerFix Plug had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have

misrepresented the safety and efficacy of the PerFix Plug.

156. Upon information and belief, Defendants' misrepresentation are designed to induce physicians to prescribe, dispense, recommend, and/or purchase the Defendants' PerFix Plug. Plaintiff and the medical community have relied upon Defendants' misrepresentations.

157. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and Plaintiff's healthcare providers, and engaged in constructive fraud in their relationship with Plaintiff and Plaintiff's medical providers. Plaintiff reasonably relied on Defendants' representations.

158. As a proximate cause of the Defendants' conduct, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

### **COUNT XIII: NEGLIGENT MISREPRESENTATION**

159. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

160. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that it's PerFix Plug had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

161. Defendants failed to exercise ordinary care in the representations concerning the PerFix Plug while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the PerFix Plug's high risk of unreasonable and dangerous adverse side effects.

162. Defendants breached their duty in representing that the Defendants' PerFix Plug

had no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

163. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the PerFix Plug had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to; pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

164. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured and sustained severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

### **LOSS OF CONSORTIUM**

165. The Plaintiffs incorporate by reference all the above paragraphs as though fully set forth herein. At the time of the implanting of the PerFix Plug in this instance, the Plaintiffs were married and the Plaintiffs continue to be married. As a result of the egregious conduct on the part of the Defendant, the Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship. As a direct and proximate result of the actions of the Defendants as described above, Mrs. Rios Vilchis has suffered a loss of consortium as that term is legally defined.

### **PUNITIVE DAMAGES ALLEGATIONS**

166. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as

if fully set forth herein.

167. Defendants failed to adequately test and study the PerFix Plug to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell PerFix Plug after obtaining knowledge and information that the product was defective and unreasonably unsafe.

168. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the PerFix Plug, Defendants developed, designed and sold the PerFix Plug, and continue to do so, because the PerFix Plug has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective PerFix Plug, including the risk of failure and serious injury, such as suffered by Plaintiff.

169. At all times relevant hereto, Defendants knew or should have known that the PerFix Plug was inherently more dangerous with respect to the risk of migration, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as the other severe and personal injuries which are permanent and lasting in nature.

170. Defendant's misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the PerFix Plug, which deprived Plaintiff and Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the PerFix Plug.

171. At all times material hereto, Defendants knew and recklessly and/or intentionally

disregarded the fact that the Defendants' PerFix Plug can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

172. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that PerFix Plug can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the medical community and the general public, including Plaintiff, of the same.

173. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the associated with PerFix Plug.

174. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of PerFix Plug with its increased risk of side effects and serious complications, Defendants continue to aggressively market the PerFix Plug to the medical community and to consumers without disclosing the true risk of such complications.

175. At the time of the Plaintiff was implanted with the PerFix Plug and since that time, Defendants knew that the PerFix Plug was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell PerFix Plug so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the PerFix Plug to members of the public including Plaintiff.

176. At all times material, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with PerFix Plug in order to

ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

177. Defendants' conduct, acts and omissions, as described herein, are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**PRAYER FOR RELIEF**

Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of profits;
- iii. Punitive or enhanced compensatory damages;
- iv. Reasonable attorneys' fees as provided by law;
- v. The costs of these proceedings, including past and future cost of the suit incurred



herein;

- vi. All ascertainable economic damages;
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

Dated: August 22<sup>st</sup>, 2019

**THE HENNING LAW FIRM**

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